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*Attorneys for Defendant Novo Nordisk Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

STATE OF MINNESOTA, BY ITS  
ATTORNEY GENERAL, KEITH  
ELLISON,

*Plaintiff,*

 $\mathbf{v}_i$ 

SANOFI-AVENTIS U.S. LLC, NOVO  
NORDISK, INC., AND ELI LILLY AND  
CO.,

*Defendants.*

Civil Action No.: 18-cv-14999-BRM-LHG

**DEFENDANT NOVO NORDISK INC.'S ANSWER TO THE  
SECOND AMENDED COMPLAINT**

Defendant Novo Nordisk Inc., by and through counsel, for its Answer to Plaintiff's Second Amended Complaint, hereby states as follows. Insofar as the Second Amended Complaint includes allegations about "Defendants," Defendant Novo Nordisk Inc. answers solely on behalf of itself, and understands that each other Defendant will file its own answer.

1. Denies the allegations, except admits on information and belief that diabetic Minnesota residents purchase insulin products, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the number of Minnesota residents with diabetes.

2. Denies the allegations, except admits that it markets insulin products; it sets the Wholesale Acquisition Cost ("WAC") for the insulin products that it markets; it negotiates with pharmacy benefit managers ("PBMs"), the negotiations and results thereof are typically confidential, and it frequently realizes revenue less than WAC for sales of its products; PBMs manage prescription drug benefits for health plans and self-insured employers; it negotiates rebates and other terms with PBMs; and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the passing of rebates from PBMs to their health plan clients.

3. Denies the allegations.

4. Denies the allegations, except admits that Plaintiff purports to seek injunctive and monetary relief, as well as civil penalties.

5. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's description of itself.

6. Admits.

7. Lacks knowledge or information sufficient to form a belief as to the truth of the description of Sanofi-Aventis U.S. LLC.

8. Lacks knowledge or information sufficient to form a belief as to the truth of the description of Eli Lilly.

9. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

10. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

11. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

12. Denies the allegations, except admits that new cases of diabetes are diagnosed in the U.S. each year, including in Minnesota, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

13. Denies the allegations, except admits that individuals diagnosed with diabetes may require daily insulin injections, may monitor their blood glucose levels, and may adhere to prescribed diets.

14. Denies the allegations, except admits that insulin is a hormone made by the pancreas that allows a person's body to process glucose, that diabetes is a disease in which the body makes little to no insulin at all (Type 1), or the body either does not make enough insulin or does not use it properly (Type 2), that insufficient insulin associated with diabetes can cause long-term complications, and that some individuals with diabetes require insulin shots.

15. Admits.

16. Denies the allegations, except admits that Defendant has been innovating improved insulin products for decades, that a number of Defendant's products are preferred diabetes treatments, that scientists have artificially produced human insulin, that scientists have developed insulin products that last longer and work better than earlier insulins, and that analog insulins allow for different absorption times and more effective management of blood sugar.

17. Denies the allegations, except admits that rapid-acting insulin is often administered immediately around mealtimes and that long-acting insulin is often administered daily, that its products include rapid-acting and long-acting insulins, and that its products include NovoLog® and Fiasp®.

18. Denies the allegations, except admits that its products include Levemir® and Tresiba®, which are branded drugs.

19. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, except admits that WAC prices for certain of its insulin products have risen over time, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Lantus.

20. Denies the allegations, except admits that WAC prices for certain of its insulin products have risen over time, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Humalog and Apidra.

21. Denies the allegations, except admits that WACs for certain of its insulin products have risen over time. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Lilly and Sanofi products.

22. Denies the allegations.

23. Denies the allegations, except admits that a growing number of people with high-deductible health plans have faced higher out-of-pocket pharmacy costs, lacks knowledge or information sufficient to form a belief as to the accuracy of the final two sentences, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

24. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the allegations regarding medical costs and pharmacy spending in Minnesota, and states that to the extent the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

25. Denies the allegations, except admits that many people with diabetes are finding it harder to pay for their healthcare, including insulin products, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the actions of doctors.

26. Denies the allegations, except admits that kidney failure, heart attacks, blindness, nerve damage, infection, amputation, and ketoacidosis are risks associated with diabetes, and that untreated or improperly managed diabetes can result in additional medical expenses.

27. Denies the allegations, except admits that pharmacies distribute drugs to customers and determine what price to charge to those customers, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning what pharmacies refer to or how Minnesota pharmacies determine prices.

28. Denies the allegations, except admits that patients with health insurance may pay a copayment or coinsurance payment for pharmaceutical products, and admits that patients may pay a monthly premium to their health plan in exchange for coverage, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning health plans' payment of fees to pharmacies.

29. Denies the allegations, except admits that many individuals' health plans have annual deductibles.

30. Denies the allegations, except admits that a growing number of people with high-deductible health plans have faced higher out-of-pocket pharmacy costs and admits that in 2019, the IRS defined a high deductible health plan as any plan with a deductible of at least \$1,350 for an individual or \$2,700 for a family. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the final sentence.

31. Denies the allegations, except admits that it sets the WAC for its insulin products; that, in accordance with federal law, WAC does not include rebates paid to PBMs or other discounts; and on information and belief, WAC typically reflects a mark-up in price.

32. Denies the allegations, except admits that it sets the WAC for its insulin products, and that Average Wholesale Price ("AWP") is a price that it does not set, and on information and belief that AWP typically reflects a mark-up above WAC.

33. Denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what AWP was originally "intended to represent" or how it is used by PBMs.

34. Denies the allegations, except admits that it publicly reports the WACs for its products, and lacks knowledge or information sufficient to form a belief as to the truth of the

allegations concerning Sanofi and Eli Lilly, reporting services, or what PBMs “rely on” to “determine the reimbursement rates that they pay to pharmacies.”

35. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Minnesota pharmacies’ practices.

36. Denies the allegations, except admits that it markets insulin products and lacks knowledge or information sufficient to form a belief as to the truth of the allegations about “entities downstream in the drug supply chain.”

37. Denies the allegations, except admits that it sets the WAC for its insulin products, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what is the “lodestar for the price charged” by other entities.

38. Denies the allegations, except admits that PBMs manage prescription drug benefits for health plans.

39. Lacks knowledge or information sufficient to form a belief as to the truth of the description of each PBM.

40. Denies the allegations, except admits that PBMs develop and maintain formularies, which are preferred drug lists created by payers, and that if drugs are excluded from formularies, those drugs may be less readily available to patients.

41. Denies the allegations, except admits that it negotiates with PBMs in exchange for formulary access and formulary position, that PBMs are able to exert considerable leverage in negotiations, and that PBMs place drugs in different tiers or place other restrictions on reimbursement for those drugs that can impact demand for them, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

42. Denies the allegations, except admits that it negotiates with PBMs over formulary access and formulary position, and that PBMs negotiate rebates and other concessions, and that the rebates it pays to PBMs are calculated as a percentage of WAC price, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding how PBMs “retain” and/or “distribute” the rebates they “collect.”

43. Denies the allegations, except admits that it negotiates with PBMs over formulary access and formulary position, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding PBMs’ behavior.

44. Denies the allegations, except admits that its contracts with PBMs are nonpublic, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second, third, and fourth sentences.

45. Denies the allegations, except admits that the terms of its rebate agreements with PBMs are nonpublic and that its WAC prices are public.

46. Denies the allegations, except admits that the drug pricing system is complex.

47. Denies the allegations, except admits that it manufactures long-acting and rapid-acting insulin products, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what PBMs “must” include to “satisfy their health plan clients’ needs.”

48. Denies the allegations, except admits that it negotiates with PBMs over formulary access and position. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi’s “calculat[ions]” or the PBMs’ “incentiv[es].”



49. Denies the allegations, except admits that if a PBM earns less in rebates for a product from a given pharmaceutical company, that PBM may choose to place a competitor's product on its formulary and may exclude other products.

50. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi.

51. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi.

52. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi.

53. Denies the allegations.

54. Denies the allegations, except admits that the 2016 amendment referenced includes that rebate percentage for Levemir.

55. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Eli Lilly.

56. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Eli Lilly.

57. Denies the allegations.

58. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi.

59. Denies the allegations, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

60. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Eli Lilly, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

61. Denies the allegations, except admits that the terms of its rebate agreements with PBMs are nonpublic.

62. Denies the allegations, except admits that its WAC prices are public and admits the WACs listed correspond to those for its NovoLOG Subcutaneous Solution 100 UNIT/ML (NDC 00169-7501-11), NovoLOG FlexPen Subcutaneous Solution Pen-injector 100 UNIT/ML (NDC 00169-6339-10), and Levemir Subcutaneous Solution 100 UNIT/ML Vial (NDC 00169-3687-12), except denies the price for the latter attributed to 8/25/2015. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Eli Lilly and Sanofi.

63. Denies the allegations, except admits that WACs for certain of Novo Nordisk's insulin products have risen over time.

64. Denies the allegations.

65. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations about what PBMs "do not mind" and about a Sanofi "analysis."

66. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what PBMs "inform [their] clients" of or "share with their health plan clients," or what "health plans are unaware" of.

67. Denies the allegations, except admits that it monitors WAC prices disclosed by competitors for competing products, lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the final sentence, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

68. Denies the allegations, except admits that WAC prices for certain of its insulin products have risen over time, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Lilly products.

69. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi and Eli Lilly, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

70. Denies the allegations, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

71. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, and states that to the extent that the allegations purport to describe particular documents, no response is required, and refers the Court to those documents, which speak for themselves, and denies any characterizations thereof.

72. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, except admits that it

markets insulins products and its WAC prices are public, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what the “vast majority of Minnesota diabetics were unaware” of.

73. Denies the allegations, except admits that its contracts with PBMs are nonpublic, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding PBMs’ practices.

74. Denies the allegations, except admits that the terms of its rebate agreements with PBMs are nonpublic, that patients with diabetes need to take insulin, and that many people with diabetes are finding it harder to pay for their healthcare, including insulin. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding what Minnesota patients are “unaware of” regarding prices or what “directly serve[s] as the benchmark on which many Minnesota patients pay for their medications.”

75. Denies the allegations, except admits that individuals without insurance pay pharmacies for pharmaceutical products, that it does not pay rebates to retail pharmacies, and that pharmacies determine what price to charge customers, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning what pharmacies refer to and the reporting services’ practices.

76. Denies the allegations, except admits that individuals with high-deductible health plans pay pharmacies for pharmaceutical products out-of-pocket during the deductible phase of their plans, and admits that it pays rebates to PBMs, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the practices of pharmacies or whether PBMs “share . . . rebates directly with individual patients.”

77. Denies the allegations, except admits that it sets the WAC for its insulin products, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the terms of PBMs' contracts with pharmacies or how pharmacies set prices. Lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi and Eli Lilly.

78. Denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi and Eli Lilly.

79. Denies the allegations.

80. Denies the allegations, except admits that a coverage "donut hole" has been an aspect of certain Medicare Part D drug plans and that during the "donut hole" participants in such plans pay a coinsurance of up to 25% of the plan's negotiated cost per prescription.

81. Denies the allegations.

82. Denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the insurance coverage of "many Minnesota patients."

83. Denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning PBMs or their "prescription drug card programs."

84. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning Sanofi and Eli Lilly.

85. Denies the allegations, and lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning PBMs and "prescription drug card programs."

86. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning PBMs' advertisement of Eli Lilly and Sanofi products or what "prescription drug card programs rely on."

87. Denies the allegations.

88. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the Minnesota Department of Corrections.

89. Denies the allegations.

90. Denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning the actions of Minnesota residents and the Minnesota Department of Corrections.

91. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

92. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

93. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning what was "apparent or obvious" to the State, its residents, or the Minnesota Department of Corrections.

94. Reiterates and reaffirms its answers to each previous allegation as if fully set out herein.

95. In light of the Court's March 12, 2021 order, Counts 1 through 12 have been dismissed.

96. In light of the Court's March 12, 2021 order, Counts 1 through 12 have been dismissed.

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417. In light of the Court's March 12, 2021 order, Counts 1 through 12 have been dismissed.

418. Reiterates and reaffirms its answers to each previous allegation as if fully set out herein.

419. Admits that Minnesota Statutes section 325F.69, subdivision 1 provides that "The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoined as provided in section 325F.70."

420. Admits that the term "merchandise" within the meaning of Minnesota Statutes section 325F.69 includes both goods and services.

421. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

422. Denies the allegation.

423. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

424. Reiterates and reaffirms its answers to each previous allegation as if fully set out herein.

425. Admits that Minnesota Statutes section 325D.44, subdivision 1, provides, in part:

“A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:

\*\*\*

(11) makes false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;

\*\*\* ; or

(13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.”

426. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

427. Denies the allegations.

428. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

429. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

430. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

431. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

432. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

433. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

434. Reiterates and reaffirms its answers to each previous allegation as if fully set out herein.

435. In light of the Court’s March 12, 2021 order, Count 15 has been dismissed.

436. In light of the Court's March 12, 2021 order, Count 15 has been dismissed.

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441. In light of the Court's March 12, 2021 order, Count 15 has been dismissed.

442. Reiterates and reaffirms its answers to each previous allegation as if fully set out herein.

443. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

444. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

445. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

446. Denies the allegations.

447. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations, except lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the prices at which Minnesota residents and the Minnesota Department of Corrections bought insulin.

448. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

449. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

450. In light of the Court's March 12, 2021 order, Counts 1 through 12 have been dismissed.

451. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

452. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

453. In light of the Court's March 12, 2021 order, Counts 1 through 12 have been dismissed.

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459. To the extent that the allegations purport to state a conclusion of law, no response is required. To the extent a response is required, denies the allegations.

#### **PRAYER FOR RELIEF**

Novo Nordisk denies that Plaintiff is entitled to any relief.

**DEMAND FOR TRIAL BY JURY**

Novo Nordisk admits that Plaintiff purports to demand a jury trial. To the extent Plaintiff purports to state a conclusion of law, no response is required.



## **DEFENSES**

Without admitting any wrongful conduct, and without assuming any burden that they would not otherwise bear, Novo Nordisk asserts the following defenses to Plaintiff's Second Amended Complaint.

1. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.

2. Plaintiff's claims are barred, in whole or in part, because they are preempted by federal law.

3. Plaintiff's claims are barred, in whole or in part, because any injuries and damages allegedly sustained by Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief were not proximately caused by any act or omission of Novo Nordisk.

4. Plaintiff's claims are barred, in whole or in part, and any recovery should be diminished, reduced, or offset, due to the comparative and/or contributory negligence of Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief.

5. Plaintiff's claims are barred, in whole or in part, because Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief, has participated in, and benefited from, the very conduct—the negotiation of rebates—that Plaintiff challenges in its Second Amended Complaint.

6. Plaintiff's claims are barred, in whole or in part, because Plaintiff has failed to identify any specific false, fraudulent, or fictitious representation or omission made by Novo Nordisk to Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief.

7. Plaintiff's claims are barred, in whole or in part, due to Plaintiff's own knowledge, and/or the knowledge of any other person or entity on whose behalf Plaintiff is seeking relief, of the information that it alleges that Novo Nordisk concealed or misrepresented.

8. Plaintiff's claims are barred, in whole or in part, because Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief, has not suffered any damage, or because the alleged damages, if any, are speculative and uncertain.

9. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing, statutory standing, and/or injury in fact.

10. Plaintiff's claims are barred by waiver.

11. Plaintiff's claims are barred by estoppel.

12. Plaintiff's claims are barred by ratification.

13. Plaintiff's claims are barred by the equitable doctrine of unclean hands.

14. Plaintiff's claims are barred by laches.

15. Plaintiff's claims are barred by the equitable doctrine of *in pari delicto*.

16. The alleged injuries and damages of Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief, if any, were caused in whole or in part by the acts and omissions of others over whom Novo Nordisk had no authority or control and/or for whom Novo Nordisk may not be held accountable.

17. The activities of Novo Nordisk alleged in the Second Amended Complaint conformed with all state and federal statutes, regulations and industry standards.

18. Plaintiff's claims are barred, in whole or in part, because Novo Nordisk's marketing materials, labeling, and pricing were not false or misleading, and therefore constitute protected commercial speech under the First Amendment to the United States Constitution.

19. Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Dormant Commerce Clause of the United States Constitution.

20. Novo Nordisk did not misrepresent or conceal any fact material to any consumer of insulin.

21. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Novo Nordisk's rights under the United States Constitution.

22. Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief, prescribing physicians, and consumers of insulin did not rely on any alleged misrepresentation or concealment by Novo Nordisk.

23. Should Novo Nordisk be held liable to Plaintiff and/or to any other person or entity on whose behalf Plaintiff is seeking relief, which liability is specifically denied, Novo Nordisk would be entitled to a set-off for the total of all amounts paid to Plaintiff and/or to any other person or entity on whose behalf Plaintiff is seeking relief from all collateral sources.

24. Plaintiff's claims may be barred or limited by the failure of Plaintiff and/or any other person or entity on whose behalf Plaintiff is seeking relief to take reasonable steps to mitigate damages, if any.

25. Plaintiff's claims are barred, in whole or in part, by lack of capacity to bring the claims asserted.

26. Plaintiff's claims are barred, to the extent Plaintiff seeks injunctive relief, because Plaintiff is not at risk of suffering irreparable harm.

27. Plaintiff is not entitled to any award of punitive damages because there is no clear and convincing evidence that Novo Nordisk acted toward Plaintiff and/or to any other person or

entity on whose behalf Plaintiff is seeking relief with oppression, fraud, malice, or gross negligence, or in any other manner justifying an award of punitive damages under federal or applicable state law.

28. An award of punitive damages would violate Novo Nordisk's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution insofar as such damages are awarded by a jury or other fact-finder that: (a) is not provided with a standard of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (b) is not adequately and clearly instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of Novo Nordisk; (d) is permitted to award punitive damages under a standard for determining liability for such damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and/or (e) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards.

29. An award of punitive damages would violate Novo Nordisk's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; and the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution insofar as such damages are imposed and determined based on anything other than Novo Nordisk's

conduct in connection with the sale of the product alleged in this litigation, or in any other way subjecting Novo Nordisk to impermissible multiple punishments for the same alleged wrong.

30. Plaintiff is not entitled to an award of costs, penalties, or attorneys' fees under any theory alleged in the Second Amended Complaint.

31. Plaintiff has failed to join indispensable parties needed under Rule 19 of the Federal Rules of Civil Procedure.

32. Novo Nordisk did not violate any legal duty owed by it to Plaintiff and/or to any other person or entity on whose behalf Plaintiff is seeking relief.

33. Novo Nordisk hereby adopts and incorporates by reference any and all other defenses asserted or to be asserted by any other defendant to the extent Novo Nordisk may share in such defense.

34. Novo Nordisk affirmatively pleads and relies upon all defenses and affirmative defenses set forth in Rules 8, 9, and 12 of the Federal Rules of Civil Procedure or under the statutes pursuant to which Plaintiff has brought suit, that are or may hereafter become applicable to the claims made herein, and expressly reserves any and all other defenses, including affirmative defenses which may become apparent during the course of discovery.

35. Novo Nordisk reserves the right to supplement this Answer with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend the Answer accordingly.

#### PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays as follows:

1. That the Second Amended Complaint be dismissed with prejudice;
2. That the Court enter judgment in favor of Novo Nordisk;

3. That the Court award Novo Nordisk its costs and expenses, including attorneys' fees; and

4. That the Court award further relief as deemed just and proper.

Dated: May 25, 2021

By: s/ Michael R. Griffinger  
Michael R. Griffinger, Esq.  
Michael R. McDonald, Esq.  
Christopher Walsh, Esq.  
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